NJOY
an Altria Company

The below information about e-cigarette products ("NJOY Products") manufactured by NJOY, LLC ("NJOY") is provided in compliance with the ingredient disclosure requirements of New York as set forth in N.Y. Pub. Health Law § 1701 and 10 N.Y.C.R.R. § 1006.2 and not for the purposes of advertising, marketing, or promoting any tobacco product:

- NJOY ACE Device[1]
- NJOY ACE Pods, Classic Tobacco, 2.4% Nicotine by Weight
- NJOY ACE Pods, Classic Tobacco, 5% Nicotine by Weight
- NJOY ACE Pods, Menthol, 2.4% Nicotine by Weight
- NJOY ACE Pods, Menthol, 5% Nicotine by Weight
- NJOY ACE Pods, Rich Tobacco, 5% Nicotine by Weight
- NJOY DAILY, Rich Tobacco, 4.5% Nicotine by Weight
- NJOY DAILY Extra, Rich Tobacco, 6% Nicotine by Weight
- NJOY DAILY, Menthol, 4.5% Nicotine by Weight
- NJOY DAILY Extra, Menthol, 6% Nicotine by Weight

The U.S. Food and Drug Administration ("FDA" or "Agency") authorized the marketing of the NJOY Products based on its determination that the science and evidence presented in NJOY's Premarket Tobacco Product Applications ("PMTA") was sufficient to meet the "Appropriate for the Protection of Public Health" ("APPH") standard and demonstrate "the benefits [of the NJOY Products], including those to adult smokers, outweigh the risks, including those to youth, resulting in a net benefit to the public health."[2]

As the Agency has explained:

> [I]n assessing APPH, FDA must consider the risks and benefits to the population as a whole, including both tobacco users and nonusers, taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products and the increased or decreased likelihood that those who do not use tobacco products will start using such products. FDA interprets the APPH standard to require a showing that

[1] NJOY also marketed NJOY ACE Devices and NJOY ACE Pods as NJOY Devices and NJOY Pods.
[2] *See* Market Granted Orders for NJOY ACE Pods and Device, Tobacco Flavors: MGO Letter from FDA CTP to NJOY LLC (STNs PM0000613.PD1-PM0000615.PD1 and PM0000622.PD1); Market Granted Orders for NJOY Pods, Menthol Flavors: Marketing Granted Order Letter from FDA CTP to Altria Client Services LLC (STNs PM0000616.PD1 and PM0000617.PD1); Market Granted Orders for NJOY Daily, Tobacco Flavors: MGO Letter from FDA CTP to NJOY LLC (STNs PM0000630-PM0000631); Marketing Granted Orders for NJOY Daily, Menthol Flavors: Marketing Granted Order Letter from FDA CTP to Altria Client Services LLC (STNs PM0000628.PD1 and PM0000629.PD1). *See also* Technical Project Lead (TPL) Review of PMTAs for NJOY ACE Pods and Device, Tobacco Flavors: Technical Project Lead (TPL) Review of PMTAs: PM0000613.PD1-PM0000615.PD1 and PM0000622.PD1; TPL Review of PMTAs for NJOY ACE Pods, Menthol Flavors: Technical Project Lead (TPL) Review of PMTAs: PM0000616.PD1 and PM0000617.PD1; TPL Review of PMTAs for NJOY Daily, Tobacco Flavors: Technical Project Lead (TPL) Review of PMTAs: PM0000630-PM0000631; TPL Review of PMTAs for NJOY Daily, Menthol Flavors: Technical Project Lead (TPL) Review of PMTAs: PM0000628.PD1 and PM0000629.PD1

> permitting the marketing of a new tobacco product would have a net benefit to public health based upon the risks and benefits to the population as a whole, which includes youth, young adults, and other vulnerable populations. In determining whether permitting the marketing of a new tobacco product would result in a net benefit to public health, FDA weighs the potential negative public health impacts (e.g., harm from initiation and use among nonusers, particularly youth) against the potential positive public health impacts (e.g., benefit from adult users of more harmful tobacco products completely switching).[3]

The following tables identify the ingredients, byproducts, and "toxic metal" constituents of heating elements in the NJOY Products, as defined by N.Y. Comp. Codes R. & Regs. Tit. 10 § 1006. NJOY previously submitted this data to FDA, and FDA analyzed it as part of its APPH determinations.[4]

Ingredient Tables[5]

Table 1: Ingredients for NJOY ACE Pod Classic Tobacco, 2.4% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Glycerin	Yes
Propylene glycol	Yes
Purified Water	No
Nicotine	Yes
Lactic Acid	No

Table 2: Ingredients for NJOY ACE Pod Classic Tobacco, 5.0% nicotine by weight and NJOY ACE Pod Rich Tobacco, 5.0% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Glycerin	Yes
Propylene glycol	Yes
Nicotine	Yes
Lactic Acid	No
Purified Water	No

[3] *See* Technical Project Lead Review of PMTAs: PM0000613.PD1 – PM0000615.PD1 and PM 0000622.PD1, dated March 10, 2020 at p.4. Accessed here: Technical Project Lead (TPL) Review of PMTAs.

[4] There are no known alternatives for the ingredients and materials identified as "chemicals of concern" and/or "toxic metals" as defined by N.Y. Comp. Codes R. & Regs. Tit. 10 § 1006.1(h)-(i). After analyzing the impact of these ingredients and materials on product users, FDA concluded that "[t]he overall toxicological risk to the users of the [NJOY Products] is lower compared to combusted cigarette smoke due to significant reductions in aerosol harmful and potentially harmful constituents (HPHCs) of the new products compared to cigarettes, as evidenced by results of nonclinical and aerosol studies." See Technical Project Lead Review of PMTAs: PM0000613.PD1 – PM0000615.PD1 and PM 0000622.PD1, dated March 10, 2020 at p.6. Accessed here: Technical Project Lead (TPL) Review of PMTAs.

[5] Pursuant to NYCRR 1006.3, other intentionally added ingredients not listed are considered proprietary and business confidential information.

Table 3: Ingredients for NJOY ACE Pod Menthol, 2.4% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Glycerin	Yes
Propylene glycol	Yes
Purified Water	No
Nicotine	Yes
Lactic Acid	No
Menthol	No

Table 4: Ingredients for NJOY ACE Pod Menthol, 5.0% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.1(b)(1)(iv)
Glycerin	Yes
Propylene glycol	Yes
Nicotine	Yes
Lactic Acid	No
Purified Water	No
Menthol	No

Table 5: Ingredients for NJOY DAILY Rich Tobacco, 4.5% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Propylene Glycol	Yes
Glycerin	Yes
Nicotine	Yes
Lactic Acid	No
Purified Water	No

Table 6: Ingredients for NJOY DAILY Extra Rich Tobacco, 6.0% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Glycerin	Yes
Propylene glycol	Yes
Nicotine	Yes
Lactic Acid	No
Purified Water	No

Table 7: Ingredients for NJOY DAILY Menthol, 4.5% nicotine by weight and NJOY DAILY Extra Menthol, 6.0% nicotine by weight

INGREDIENT	Chemical of Concern, 10 NYCRR 1006.1(b)(1)(iv)
Propylene Glycol	Yes
Glycerin	Yes
Nicotine	Yes
Lactic Acid	No
Menthol	No

Byproduct Tables[6]

Table 8: Byproducts for NJOY ACE Pod Classic Tobacco, 2.4% nicotine by weight; NJOY ACE Pod Classic Tobacco, 5.0% nicotine by weight; NJOY ACE Pod Rich Tobacco, 5.0% nicotine by weight; NJOY ACE Pod Menthol, 2.4% nicotine by weight; and NJOY ACE Pod Menthol, 5.0% nicotine by weight

BYPRODUCTS	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Octamethylcyclotetrasiloxane	No
Decamethylcyclopentasiloxane	No
Acetaldehyde	Yes
Acetone	Yes
Acetyl propionyl	Yes
Acrolein	Yes
Anabasine[A]	Yes
Arsenic	Yes
Benzyl acetate[B]	Yes
Butyraldehyde	Yes
Cadmium	Yes
Chromium	Yes
Cobalt	Yes
Crotonaldehyde	Yes
Diacetyl	Yes
Diethylene glycol	Yes
Ethyl acetate[C]	Yes
Ethylene glycol	Yes
Formaldehyde	Yes
Glycidol	Yes

[6] Pursuant to 10 N.Y.C.R.R. §1006.2(b)(v) relating to evaluations of the availability of alternative ingredients in vapor products or alternatives for constituents of any heating element in e-cigarettes, such evaluations have not been performed for any of the products. After analyzing the impact of these ingredients and materials on product users, FDA concluded that "[t]he overall toxicological risk to the users of the [NJOY Products] is lower compared to combusted cigarette smoke due to significant reductions in aerosol harmful and potentially harmful constituents (HPHCs) of the new products compared to cigarettes, as evidenced by results of nonclinical and aerosol studies." (see Technical Project Lead Review of PMTAs: PM0000630 – PM0000631, dated March 30, 2020, at p.6)

BYPRODUCTS	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Iron	Yes
Isoamyl acetate	Yes
Isobutyl acetate	Yes
Lead	Yes
Mercury	Yes
Nickel	Yes
NNK[B]	Yes
Nornicotine	Yes
Phenol	Yes
Propionic acid	Yes
Propylene oxide	Yes
Selenium	Yes
Toluene	Yes

[A] This constituent is only present in NJOY ACE Pod Classic Tobacco, 5.0% nicotine by weight and NJOY ACE Pod Rich Tobacco 5.0% nicotine by weight
[B] This constituent is only present in NJOY ACE Pod Menthol, 2.4% nicotine by weight
[C] This constituent is only present in NJOY ACE Pod Classic Tobacco, 2.4% nicotine by weight and NJOY ACE Pod Rich Tobacco 5.0% nicotine by weight

Table 9: Byproducts for NJOY DAILY Rich Tobacco, 4.5% nicotine by weight; NJOY DAILY Extra Rich Tobacco, 6.0% nicotine by weight; NJOY DAILY Menthol, 4.5% nicotine by weight; NJOY DAILY Extra Menthol, 6.0% nicotine by weight

BYPRODUCTS	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Octamethylcyclotetrasiloxane	No
Decamethylcyclopentasiloxane	No
Acetaldehyde	Yes
Acetone	Yes
Acetyl propionyl[A]	Yes
Acrolein	Yes
Arsenic	Yes
Benzyl acetate[B]	Yes
Butyraldehyde	Yes
Cadmium	Yes
Chromium	Yes
Cobalt	Yes
Crotonaldehyde[A]	Yes
Diacetyl	Yes
Ethyl acetate	Yes
Ethylene glycol[A]	Yes
Formaldehyde	Yes
Glycidol	Yes
Irganox 1076	No

BYPRODUCTS	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Isoamyl acetate	Yes
Isobutyl acetate	Yes
Lead	Yes
Mercury	Yes
Methyl acetate[C]	Yes
n-Butanol	Yes
Nickel	Yes
NNK[D]	Yes
Nornicotine	Yes
Phenol	Yes
Propionic acid	Yes
Selenium	Yes
Toluene	Yes

[A] This constituent is not present in NJOY DAILY Rich Tobacco, 4.5% nicotine by weight
[B] This constituent is only present in NJOY DAILY Rich Tobacco, 4.5% nicotine by weight and NJOY DAILY Menthol, 4.5% nicotine by weight
[C] This constituent is only present in NJOY DAILY Extra Rich Tobacco, 6.0% nicotine by weight
[D] This constituent is only present in NJOY DAILY Rich Tobacco, 4.5% nicotine by weight

Toxic Metal Constituents of Heating Element Tables

Table 10: Toxic metal constituents of heating element for NJOY ACE Pod Classic Tobacco, 2.4% nicotine by weight; NJOY ACE Pod Classic Tobacco, 5.0% nicotine by weight; NJOY ACE Pod Rich Tobacco, 5.0% nicotine by weight; NJOY ACE Pod Menthol, 2.4% nicotine by weight; and NJOY ACE Pod Menthol, 5.0% nicotine by weight

Toxic Metal Constituents of Heating Element	Chemical of Concern, 10 NYCRR 1006.2(b)(1)(iv)
Nickel	Yes
Iron	Yes
Chromium	Yes

Table 11: Toxic metal constituents of heating element for NJOY DAILY Rich Tobacco, 4.5% nicotine by weight; NJOY DAILY Extra Rich Tobacco, 6.0% nicotine by weight; NJOY DAILY Menthol, 4.5% nicotine by weight; NJOY DAILY Extra Menthol, 6.0% nicotine by weight

Toxic Metal Constituents of Heating Element	Category 10 NYCRR 1006.1(b)(1)(iv)
Nickel	Yes
Chromium	Yes

Investigations and research performed by or for the manufacturer concerning the effects on human health of the product or its ingredients.

NJOY has extensively investigated and researched the effects NJOY Products may have on human health, including through in-vitro toxicology testing, toxicological risk assessment,

pharmacokinetic studies, puff topography, user surveys, and additional data available in the scientific literature. FDA's examination confirmed that the available data are sufficient to establish that marketing the NJOY Products is APPH given their net benefit to the public health.

As FDA explained:

> "[B]efore determining that permitting the marketing of a tobacco product would be APPH, FDA also takes into account whether the applicant has provided sufficient information regarding product design, chemistry, stability, manufacturing controls including process controls and quality assurance procedures, toxicology, abuse liability, and other factors that can impact the product's risks and benefits to individual users, including relative to those of other tobacco products on the market."[7]

Chemical and Physical Characterization:

NJOY submitted extensive research and analysis to FDA as a part of PMTAs that enabled the Agency to evaluate, among other things: the levels of constituents present in the NJOY Products and how they may change over the course of their shelf life; impact from the materials contacting the NJOY Products' e-liquid or aerosol; the ways in which NJOY's sourcing, manufacturing and quality controls adhere to relevant standards; and a comparison of the constituent levels found in the NJOY Products relative to those in combustible cigarettes. Taken together, this evidence showed that the NJOY Products' aerosol contains far fewer constituents than combustible cigarette smoke – an important component in the Agency's evaluation of potential health risks and determination that the NJOY Products are APPH.

Toxicological Studies:

NJOY conducted and submitted extensive toxicological analyses to FDA demonstrating the effects of the NJOY Products' aerosols on living cells. These analyses assessed the mutagenic, genotoxic, and cytotoxic potential of the aerosol generated by the NJOY Products by using in-vitro methods and observing any genetic mutations, DNA damage, and cell damage, respectively. Study results showed that the NJOY Products were not mutagenic or genotoxic and were only cytotoxic at substantially large doses. By contrast, combustible cigarettes were mutagenic, genotoxic, and cytotoxic across the range of doses studied. These toxicity studies suggest that the NJOY Products produce fewer toxic effects than those observed from combustible cigarette exposures and support the FDA's APPH determination.

Human Studies:

The NJOY Products were evaluated through a series of clinical studies, including Abuse Liability, Pharmacokinetic (PK), and Topography Studies, Human Factors and Usage Studies, Label Comprehension Studies, and a User Study. The results of this testing program are summarized below:

[7] See Technical Project Lead Review of PMTAs: PM0000613.PD1 – PM0000615.PD1 and PM 0000622.PD1, dated March 10, 2020 at p.5. Accessed here: Technical Project Lead (TPL) Review of PMTAs.

- Abuse Liability: NJOY considered data relevant to the assessment of abuse liability, which is defined as the likelihood of individuals developing dependence on a tobacco product. The PK and topography data support a conclusion that nicotine uptake and abuse liability for the NJOY Products, regardless of flavor or nicotine concentration, is lower than combustible cigarettes, and likely comparable to or lower than other market leading ENDS products.

- User Topography: NJOY recorded topography parameters — that is, how people tend to *use* the products — by measuring puff volume and duration, including how often a user takes a puff. The data indicates that actual use patterns of the NJOY Products by human subjects are milder in puff volume and duration than both the non-intense and intense puffing regimes used in product characterization, stability testing, and risk assessments for these products. As a result, the puffing regimes used in the product testing studies likely overestimate the exposure to constituents that NJOY product users realistically experience.

- Label Comprehension: Subjects understood from the label and instructions for use the risks associated with use of the NJOY Products.

- Adverse Experiences (AEs): NJOY collected and submitted to FDA information on any unfavorable physical or psychological effects that occurred during clinical studies of the NJOY Products. In addition, NJOY has continued collecting and submitting information on AEs related to the NJOY Products as a part of its post-market requirements for authorized products. These AEs were consistent with those observed with other ENDS products in those studies and in the broader scientific literature.

Population Modeling:

NJOY also conducted and submitted population modeling to FDA estimating the potential public health impact of issuing market authorizations for the NJOY Products. The outcomes of these models demonstrated that marketing the NJOY Products is expected to have a positive public health impact on the population as a whole and supports the Agency's APPH determination.

Manufacturer Name and Address:

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Questions – Contact Us